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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SEHARASEYON, JEGATHEESAN	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/691,653	ESCARY, JEAN-LOUIS	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *1-26,29-35,38-41,43-46,49 and 50* is/are withdrawn from consideration.

5)☒ Claim(s) *27,28,42,47 and 48* is/are allowed.

6)☒ Claim(s) *36 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the amendment and remarks filed on 4/7/06. Claims 45-50 have been added. Claims 5, 13, 23, 27, 28, 33, 36-39 and 42 have been amended. Therefore, claims 1-50 are currently pending. Claims 1-26, 29-35, 38-41, 43-46 and 49-50 are withdrawn. Claims 27, 28, 36, 37, 42, 47and 48 are examined.

2. Newly submitted claims 45, 46, 49 and 50 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The elected invention is drawn to polypeptide claims, whereas claims 45, 46, 49 and 50 are drawn to polynucleotide compositions. Inventions are different from each other because polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules than polypeptides, which are composed of amino acids; any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In addition, polypeptides can be made by another materially different process than from recombinant polynucleotide expression, such as chemical synthesis or isolation/purification from natural sources.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 45, 46, 49 and 50 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. The change of title is acknowledged.

4. Receipt of the certified copy of the priority document is acknowledged.

5. Receipt of the copies of the Oath/Declaration is acknowledged.

6. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

7. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn. Thus, claims 27, 28, 42, 47 and 48 are allowed.

8. Claims 27, 28, 42, 47 and 48 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 36-37, directed to the process of making or using the allowable product, previously withdrawn from consideration as a result of a restriction requirement, is hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 1-26, 29-35, 38-41, 43-46 and 49-50, directed to the invention(s) of 1-6, 8-12 and 14-16 do not require all the limitations of an allowable product claim, and are NOT been rejoined.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, **the restriction requirement between groups 7 and 13 as set forth in the Office action mailed on 6/21/2005 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claims including all the limitations of an allowable product claim or rejoined process claim are presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting

rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Objections

6. Claims 36 and 37 are objected to because of the following informalities: The claims include limitations form unelected invention of claim 29. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands,* 858 F.2d at 737, 8 USPQ2d at 1404. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level

of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claim 36 is drawn to treating or preventing a disease or disorder linked to interferon alpha-17 by administering a polypeptide of SEQ ID NO: 2. Applicants have evaluated the antiviral and antiproliferative activity of the interferon alpha-17 polypeptide comprising the G45R mutation (pages 45-49). However, the specification as filed is insufficient to enable one of skilled in the art to practice the claimed invention of treating or preventing a disease or disorder linked to interferon alpha-17 without an undue amount of experimentation because the specification and the prior art have not established the interferon alpha-17 linked disorders. Thus the pathology of a disease or disorder linked to interferon alpha-17 are not known. For example, CFTR gene is linked to cystic fibrosis and Duchene Muscular Dystrophy gene is linked to DMD. Even if a disease or disorder linked to interferon alpha-17 are known it is not clear if it can be prevented.

If one skilled in the art is not guided as to the pathology of the a disease or disorder linked to interferon alpha-17, then the skilled artisan is also not guided as to how to use methods for the treatment or prevention using the compositions comprising these polypeptides. Since, there is inadequate guidance as to the nature of the invention, it is merely an invitation to the artisan to use the current invention as a starting point for further experimentation to try various disease or disorder linked to interferon alpha-17 for prevention and treatment. In addition, because there are no

working examples provided describing diseases or models, it would require an undue amount of experimentation to one of skill in the art to practice the claimed invention. In addition, there are no mechanism(s) associated with a disease or disorder linked to interferon alpha-17 recited in the claims. While mechanism is not required, it can allow extrapolation of enablement to non-exemplified embodiments.

Given the breadth of claim 36 in light of the unpredictability of the art as determined by the lack of working examples, the level of skill of the artisan, and the lack of guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention for a method of treatment or method of preventing a disease or disorder linked to interferon alpha-17 by administering interferon alpha-17 polypeptides.

8. Claim 37 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for treating (antiviral activity against vesicular stomatitis virus (VSV) *in vitro* and against Encephalomyocarditis virus (EMCV) *in vivo* (mouse model)), does not reasonably provide enablement for the treatment against all viral diseases or preventing viral diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 37 is drawn to treating or preventing a viral disease by administering a polypeptide of SEQ ID NO: 2. Applicants have evaluated the antiviral and antiproliferative activity of the interferon alpha-17 polypeptide comprising the G45R

mutation (pages 45-49). Specifically, Applicants demonstrate antiviral activity against vesicular stomatitis virus (VSV) *in vitro* and against Encephalomyocarditis virus (EMCV) *in vivo* (mouse model). However, the specification as filed is insufficient to enable one of skilled in the art to practice the claimed invention of treating or preventing a viral disease without an undue amount of experimentation because the specification and the prior art have not treated or prevented all viral diseases.

Applicant has not disclosed how to use the claimed invention to treat or prevent all viral diseases of the subjects. There is insufficient evidence of the invention with respect to the *in vivo* operability of the claimed invention. In addition, there is no guidance provided in choosing the treatment regimen with therapeutically effective amount for administering to the subjects. Pharmaceutical therapies are unpredictable for the following reasons; (1) the proteins may be inactivated before producing an effect, i.e. such as proteolytic degradation, immunological inactivation or due to an inherently short half life protein; (2) the protein may otherwise not reach the target area because, for example, the protein may not be able to cross the mucosa; (3) other functional properties, known or unknown, may make the protein unsuitable for *in vivo use*, i.e. may produce adverse side effects prohibitive to the using of such treatment.

Since, there is inadequate guidance as to the nature of the invention, it is merely an invitation to the artisan to use the current invention as a starting point for further experimentation for preventing or treating all viral diseases by administering the polypeptide of the instant invention. In addition, because there is only single *in vivo*

working examples provided describing diseases or models it would require an undue amount of experimentation to one of skill in the art to practice the claimed invention.

Given the breadth of claim 37 in light of the unpredictability of the art as determined by the lack of working examples, the level of skill of the artisan, and the lack of guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention for a method of treatment or method of preventing all viral diseases by administering interferon alpha-17 polypeptides.

9. Claims 27, 28, 42, 47 and 48 are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS 06/06

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud